



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,548	10/22/1999	DAVID ROBBINS	DEX-0054	2041

7590 05/01/2002

JANE MASSEY LICATA
66 E MAIN STREET
MARLTON, NJ 08053

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,548

Applicant(s)

ROBBINS ET AL.

Examiner

Joseph Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/4/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1632

DETAILED ACTION

Applicants' amendment filed February 4, 2002, paper number 20, has been received and entered. Claim 1 has been canceled. Claims 2 and 3 have been amended. Claim 9 has been added. Claims 2, 3 and 9 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter Rejection

Claims 2 and 3 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

It is noted that claim 1 has been canceled removing the reference to the GenBank Accession numbers which was the basis of the new matter rejection. Applicants' amendment has obviated the basis of rejection, therefore the rejection is withdrawn.

Art Unit: 1632

Written Description

Claims 2 and 3 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

It is noted that claim 1 has been canceled removing the reference to a 'variant human MLH1 or MSH2'. Applicants' amendment has obviated the basis of rejection, therefore the rejection is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Amendments to the claims has obviated the basis of the rejection.

Claim 2, 3 and 9 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 9 is vague, unclear and confusing in the

Art Unit: 1632

recitation of an 'oligonucleotide probe to' hMLH and hMSH mutants. It is noted that the specification indicates that the specific mutations found in the hMLH and hMSH genes of patients have been referred to by the various terms recited in the claims, however this portion of the specification does not define or set forth a specific oligonucleotide which is represented by these terms. The present specification provides a general teaching for oligonucleotides for uses in PCR and hybridization, however there is no specific teaching to what or how a particular oligonucleotide would be defined for a particular mutant. The claims are vague and unclear because in light of the general teaching in the specification the metes and bounds of what is encompassed by the claim are not adequately defined. For example, it is unclear if an oligonucleotide outside a particular mutation would be encompassed by the instant claim if it were used to detect a mutation in a gene. It is noted that the present disclosure teaches that the claimed oligonucleotide clearly encompass sequences outside a given mutation, though a preferred embodiment would include 'probes [which] are complementary to at least a portion of the variant hMLH1 and hMSH2 genes' (page 18, lines 1-2). Further, it is noted that hMLH1 mutant 2 and hMSH2 mutant 1 are deletion mutants, and it is unclear how one can have an oligonucleotide to something which is not present. It appears that the claim may be intended to encompass oligonucleotides which can identify the particular and specific mutations taught in the present disclosure, however it is unclear if this includes only oligonucleotides which comprise the mutation within its sequence or other oligonucleotides to non-mutant sequences which can be used in assays to detect the presence or absence of the mutant. The claim is indefinite because

Art Unit: 1632

neither the claim nor the specification clearly sets forth the metes and bounds for any characteristic of an oligonucleotide encompassed by the instant claims.

Claims 2 and 3 are included in the basis of the rejection because they are dependent on the use of the oligonucleotides encompassed by claim 9. As noted above, the oligonucleotides encompassed by claim 9 do not even have to comprise a particular mutation. Further, some of the mutations are directed to deletions, and the methods directed to using an oligonucleotide to detect the presence of a deletion are confusing since there is nothing to detect. Furthermore, the claims are vague and unclear since they encompass use of oligonucleotides to normal sequences and/or very large oligonucleotide probes which would not be indicative of any mutation since the oligonucleotides would bind and detect any DNA or RNA of the MLH1 and MSH2 genes.

More clearly defining the metes and bounds of the oligonucleotide probes of claim 9 would obviate the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1632

Claims 2, 3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber *et al.*

It is noted that new claim 9 includes hMLH mutant 2 which was previously indicated to be specifically anticipated by the cited reference (see office action mailed June 6, 2000, paper number 8, pages 10-12). With respect to the remaining mutations, the probes encompassed by claim 9 can reasonably be interpreted to encompass sequences which are not overlapping or complementary to the mutation specifically described, as discussed above in the 112, second paragraph rejections. Further, because claims 2 and 3 depend on claim 9, the methods would encompass any form of screening of a DNA or RNA sample, because the screening does not involve identifying any specific mutation, only the presence or absence of binding, the presence or the absence of a mutation is indicative of the screening method.

Weber *et al.* teach a method and the appropriate oligonucleotides to detect mutations in the MLH1 and MSH2 genes. Further, the detected mutations are correlated with heredity nonpolyposis colorectal cancer (whole document, particularly Table 1 and 2). Therefore, the claim is anticipated by Weber *et al.*

Claims 2, 3 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Liskay *et al.*

It is noted that new claim 9 includes hMLH mutant 2 which was previously indicated to be specifically anticipated by the cited reference (see office action mailed June 6, 2000, paper

Art Unit: 1632

number 8, pages 10-12). With respect to the remaining mutations, the probes encompassed by claim 9 can reasonably be interpreted to encompass sequences which are not overlapping or complementary to the mutation specifically described, as discussed above in the 112, second paragraph rejections. Further, because claims 2 and 3 depend on claim 9, the methods would encompass any form of screening of a DNA or RNA sample, because the screening does not involve identifying any specific mutation, only the presence or absence of binding, the presence or the absence of a mutation is indicative of the screening method.

Liskay *et al.* teach a method and the appropriate oligonucleotides for the detection of mutations in MLH1 and MSH2 which are associated and predictive of heredity nonpolyposis colorectal cancer (whole document and in particular figure 1, and sequences of figures 2-5, 13-16). Therefore, the claim is anticipated by Liskay *et al.*

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1632

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630